

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *et al.*,

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

CIV. NO. 20-1320

**PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO MOTION TO INTERVENE**

TABLE OF AUTHORITIES

Cases

<i>Akiachak Native Cnty. v. U.S. Dep't of Interior,</i> 584 F. Supp. 2d 1 (D.D.C. 2008)	7
<i>Audubon Naturalist Soc'y of the Cent. Atlantic States, Inc., v. U.S. Dep't of Transp.,</i> 524 F. Supp. 2d 642 (D. Md. 2007)	7
<i>Brackeen v. Zinke,</i> No. 4:17-CV-00868-O, 2018 WL 10561984 (N.D. Tex. June 1, 2018)	11
<i>Club v. Glickman,</i> 82 F.3d 106 (5th Cir. 1996)	7
<i>Donaldson v. United States,</i> 400 U.S. 517 (1971)	2
<i>Fletcher v. Lamone,</i> No. RWT 11CV3220, 2011 WL 6097770 (D. Md. Dec. 5, 2011)....	2
<i>Houston Gen. Ins. Co. v. Moore,</i> 193 F.3d 838 (4th Cir. 1999)	2
<i>Lee v. Va. Bd. of Elections,</i> No. 3:15CV357-HEH, 2015 WL 5178993 (E.D. Va. Sept. 4, 2015)....	2, 5
<i>Little Rock Family Planning Servs. v. Rutledge,</i> 397 F. Supp. 3d 1213 (E.D. Ark. 2019)	9
<i>Makhteshim Agan of N. Am., Inc. v. Nat'l Marine Fisheries Servs.,</i> No. 8:18-CV-00961-PWG, 2018 WL 5846816 (D. Md. Nov. 8, 2018)	8, 10, 12
<i>McHenry v. Comm'r,</i> 677 F.3d 214 (4th Cir. 2012)	3, 13
<i>Mir v. Smith,</i> 521 F. Supp. 446 (N.D. Ga. 1981)	11
<i>MKB Mgmt. Corp. v. Burdick,</i> 855 N.W.2d 31 (N.D. 2014)	9
<i>N.C. State Conference of NAACP v. Cooper,</i> 332 F.R.D. 161 (M.D.N.C. 2019)	12, 13
<i>Ohio Valley Envtl. Coal., Inc. v. McCarthy,</i> 313 F.R.D. 10 (S.D.W.Va. 2015).....	3, 4

<i>Outdoor Amusement Bus. Ass'n. v. Dep't of Homeland Sec.,</i> No. CV ELH-16-1015, 2017 WL 2778820 (D. Md. June 26, 2017)	10
<i>Pa. Nat'l Mut. Cas. Ins. Co. v. Perlberg,</i> 268 F.R.D. 218 (D. Md. 2010).....	9
<i>Planned Parenthood of Ind. & Ky. v. Comm'r,</i> 273 F. Supp. 3d 1013 (S.D. Ind. 2017), <i>aff'd</i> , 896 F.3d 809 (7th Cir. 2019)	9
<i>Richman v. First Woman's Bank,</i> 104 F.3d 654 (4th Cir. 1997)	2
<i>Sea-Land Serv., Inc. v. Dep't of Transp.,</i> 137 F.3d 640 (D.C. Cir. 1998).....	4
<i>Spring Const. Co. v. Harris,</i> 614 F.2d 374 (4th Cir. 1980)	11
<i>Standard Heating & Air Conditioning Co. v. City of Minneapolis,</i> 137 F.3d 567 (8th Cir. 1998)	4
<i>Stuart v. Huff,</i> 706 F.3d 345 (4th Cir. 2013)	<i>passim</i>
<i>Teague v. Bakker,</i> 931 F.2d 259 (4th Cir. 1991)	2, 6
<i>Trbovich v. United Mine Workers,</i> 404 U.S. 528 (1972)	7
<i>United States v. North Carolina,</i> No. 1:13CV861, 2014 WL 494911 (M.D.N.C. Feb. 6, 2014).....	10
<i>Va. Uranium, Inc. v. McAuliffe,</i> No. 4:15-CV-00031, 2015 WL 6143105 (W.D. Va. Oct. 19, 2015).....	12
<i>Virginia v. Westinghouse Elec. Corp.,</i> 542 F.2d 214 (4th Cir. 1976)	7, 12
<i>Wash. Elec. v. Mass. Mun. Wholesale Elec.,</i> 922 F.2d 92 (2d Cir. 1990)	4
<i>Waterkeeper All., Inc. v. Wheeler,</i> 330 F.R.D. 1 (D.D.C. 2018).....	7
<i>WildEarth Guardians v. Jewell,</i> 320 F.R.D. 1 (D.D.C. 2017).....	7

<i>Wildearth Guardians v. Salazar,</i> 272 F.R.D. 4 (D.D.C. 2010).....	7
---	---

Statutes

Ind. Code § 16-34-2-1	5, 6
-----------------------------	------

Rules

Fed. R. Civ. P. 24.....	<i>passim</i>
-------------------------	---------------

Other Authorities

U.S. Dep’t of Health & Human Servs., Secretary Azar Statement on March for Life (Jan. 23, 2020), https://www.hhs.gov/about/news/2020/01/23/hhs-secretary-azar-statement-on-march-for-life.html	8
--	---

U.S. Food & Drug Admin., Mifeprex (Mifepristone) Tablets (Dec. 15, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020TOC.cfm	10
--	----

U.S. Food and Drug Admin., <i>Medical Review of Mifeprex</i> (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf	6
--	---

U.S. Food & Drug Admin., <i>5 Charged in \$2.8 Million Dark Web Drug Trafficking, Money Laundering Conspiracy</i> (Jan. 15, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/5-charged-28-million-dark-web-drug-trafficking-money-laundering-conspiracy	8
---	---

I. INTRODUCTION

This litigation raises a narrow question: whether a U.S. Food and Drug Administration (“FDA”) regulation on mifepristone, a medication used for early abortion and miscarriage care, imposes constitutional injury during the COVID-19 pandemic by forcing patients to travel to a hospital, clinic, or medical office for the sole purpose of picking up the medication and signing a form. *See, e.g.*, ECF No. 1 (hereinafter “Compl.”) ¶¶ 6-7, 97, 106. In support of their pending motion for a preliminary injunction, Plaintiffs offered illustrative testimony from physicians in multiple states that the FDA’s Risk Evaluation and Mitigation Strategy (“REMS”) for mifepristone is the singular barrier preventing them from exercising their clinical judgment to enable patients to obtain this care without an unnecessary and risky in-person visit during the pandemic. *See* Pls.’ Mem. in Support of Mot. for Prelim. Inj., at Exhibits 3-7. Twenty-two States and the District of Columbia filed an amicus brief in support of Plaintiffs’ motion, explaining why their residents urgently need this relief during the pandemic. *See* ECF No. 43.

Ten States (“the States”) now ask this Court to allow them to participate in this litigation—not as *amici* like the others, but as additional defendants. The States’ principal theory for why this Court should more than triple the number of defendants in this emergency matter is that, while the States and Federal Defendants share an “ultimate objective to defend the constitutionality of the FDA’s regulations,” the States also want to “safeguard their own abortion laws,” States’ Mem. in Support of Mot. to Intervene (hereinafter “Mot.”) at 10 — state laws that Plaintiffs do not challenge here, and that, far from “rely[ing] on the REMS,” *id.* at 5, impose restrictions beyond the FDA’s.

The proposed intervenors fail to address critical aspects of the intervention standard as established by the Fourth Circuit, and have not complied with Rule 24. In addition to these legal shortcomings, this Court should deny the States’ motion for intervention because the States’

asserted interests are not direct, substantial, or impaired; the States cannot make a strong showing of inadequacy of representation; and allowing the States to participate as parties would needlessly complicate this matter with questions of state law not challenged by this narrow litigation.

II. ARGUMENT

A. The States Are Not Entitled to Intervene as of Right under FCRP 24(a)

Movants may intervene as of right only if, in addition to timeliness, they demonstrate that “they possess a ‘direct and substantial interest’ in the subject matter of the litigation”; “the denial of intervention would significantly impair or impede their ability to protect their interests”; and “their interests are not adequately protected by the existing parties.” *Fletcher v. Lamone*, No. RWT 11CV3220, 2011 WL 6097770, at *2 (D. Md. Dec. 5, 2011) (citing *Richman v. First Woman’s Bank*, 104 F.3d 654, 658–59 (4th Cir. 1997)). Failure to satisfy any one of these requirements is fatal to intervention. See *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999). The States do not, and cannot, satisfy this standard.

1. The States’ Interests Are Neither Direct, Substantial, Nor Impaired.

The States cannot demonstrate that they possess a “‘significantly protectable interest’” that could be “impaired or impeded by disposition” of this action. *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991) (quoting *Donaldson v. United States*, 400 U.S. 517, 531 (1971)). Their speculative concerns regarding the enforceability of independent state laws and hypothetical patient harm leading to increased Medicaid expenditures, do not constitute a “direct ‘rather than remote or contingent’ interest.” *Lee v. Va. Bd. of Elections*, No. 3:15CV357-HEH, 2015 WL 5178993, at *2 (E.D. Va. Sept. 4, 2015) (citation omitted). Moreover, “the impairment prong is not met” where, as here, the States “could adequately protect [their] interests in the action by participating as amicus curiae.” *Ohio Valley Envtl. Coal., Inc. v. McCarthy*, 313 F.R.D. 10, 26 (S.D.W. Va. 2015) (citing

McHenry v. Comm'r, 677 F.3d 214, 227 (4th Cir. 2012)).

This litigation challenges only the FDA restrictions that require patients seeking abortion or miscarriage care to make an unnecessary trip to a hospital, clinic, or medical office, during the pandemic just to pick up their mifepristone prescription and sign a form. *See Compl.* ¶¶ 6-7, 97, 106. Nevertheless, the States' principal argument is that intervention is necessary to enable them to "safeguard their own abortion laws." Mot. at 10. The States raise particular concern about the potential impact of this litigation on state laws imposing in-person requirements for abortion beyond what the REMS requires—*i.e.*, laws requiring an in-person examination before medication abortion may be prescribed, *see* Mot. at 2-4 (discussing Indiana, Alabama, Arkansas and Mississippi), and laws requiring the patient to be in the physical presence of the prescriber when taking the mifepristone, *see* Mot. at 3-4 (discussing Kentucky, Louisiana, Mississippi, Missouri, Nebraska and Oklahoma). The challenged REMS does not impose either such restriction: the FDA allows clinicians to exercise their professional judgment in assessing patient eligibility either remotely or in person, and the FDA permits patients to take the medication unsupervised at home. The States' argument that their laws "rely on" the *less* stringent FDA restrictions defies logic.

Notwithstanding that this lawsuit does not challenge state laws that layer additional restrictions on top of the mifepristone REMS, and that may necessitate an in-person trip (for abortion care) regardless of the REMS, the States speculate that "the enforceability of these state laws could be impaired, depending on the grounds and scope of any relief this Court grants." Mot. at 5-6. They argue that, "in turn, if intervention is not allowed, all Proposed Intervenors will be impaired in their ability to adequately protect the interests of their citizens from the increased health and other risks that will result from unsupervised administration of mifepristone," ECF No. 46 (hereinafter "Notice of Intent") at 2—unsupervised self-administration that the FDA already

permits, Compl. ¶¶ 7, 98-99; that many of these States already prohibit, *see* Mot. at 2-4; and that, in any event, has no bearing on whether a patient will experience any exceedingly rare risks hours or days after taking the medication, *see* Compl. ¶ 100. The States argue further that, “[i]n turn, complications from these health risks may put a burden on Proposed Intervenors’ Medicaid systems, increasing the cost to taxpayers.” Notice of Intent 2; *accord* Mot. at 9.¹

It is always the case that new legal precedent could impact future litigation; were that sufficient alone to establish injury, Rule 24 (and Article III) would be toothless. *Cf. e.g., Sea-Land Serv., Inc. v. Dep’t of Transp.*, 137 F.3d 640, 648 (D.C. Cir. 1998) (“[M]ere precedential effect within an agency is not, alone, enough to create Article III standing,” even in cases where future litigation is “foreseeable”) (citations omitted)). Instead, the speculative injuries the States assert here are precisely the type of contingent interests courts routinely reject in evaluating motions for intervention. *See, e.g., Wash. Elec. v. Mass. Mun. Wholesale Elec.*, 922 F.2d 92, 97 (2d Cir. 1990) (“An interest that is remote from the subject matter of the proceeding, or that is contingent upon the occurrence of a sequence of events before it becomes colorable, will not satisfy the rule.”); *Standard Heating & Air Conditioning Co. v. City of Minneapolis*, 137 F.3d 567, 571 (8th Cir. 1998) (denying intervention where interests were “too speculative to be ‘direct, substantial and legally protectable’ interests as required by Rule 24(a)(2)); *Ohio Valley Environ. Coal., Inc. v. McCarthy*, 313 F.R.D. 10 (S.D.W. Va. 2015) (denying intervention where asserted injury would not occur, if at all, until “multiple interim steps have been taken”); *Lee*, 2015 WL 5178993, at *2 (denying intervention where impact of election-related litigation on candidate in future election was speculative).

¹ The States nowhere discuss the Medicaid costs resulting from COVID-19-related care or from carrying a pregnancy to term.

Nor does Indiana's argument that this litigation could "raise questions" regarding an Indiana law that refers obliquely to the REMS's Patient Form requirement establish a direct and substantial interest. Notice of Intent at 2. That statute provides:

In accordance with FDA guidelines, the physician shall provide the pregnant woman with a copy of the manufacturer's instruction sheets and require that the pregnant woman sign the manufacturer's patient agreement form. The physician shall retain a copy of the signed patient agreement form . . . in the patient's file.²

Ind. Code § 16-34-2-1. Plaintiffs do not challenge the substance of the Patient Form requirement; this lawsuit challenges the federal requirement "only to the extent" that it precludes full relief from the in-person dispensing requirement by forcing clinicians to provide a copy of the form in person (rather than electronically or by mail) and obtain a signature in person (rather than electronically or by documenting oral consent in the patient's record). Compl. ¶ 127. And in Indiana the calculus is different: Indiana law separately requires an in-person examination, Ind. Code § 16-34-2-1; therefore, an Indiana physician can provide the form and obtain the patient's signature when the patient is already at their office getting other medical care, as required by state law.

Indiana claims that a ruling here may "confus[e]" its residents about the meaning of this statute. Mot. at 6. But any risk of confusion long predates Plaintiffs' litigation. While the statute purports to impose these requirements "[i]n accordance with FDA guidelines," it also requires that a *physician* provide the form and obtain the patient's signature. Ind. Code § 16-34-2-1. Such requirements are not in the REMS: rather, the FDA authorizes nurse practitioners and other qualified clinicians to prescribe mifepristone, including reviewing the form and obtaining the

² Indiana also requires the clinician to retain a signed copy of the "physician's agreement form required by the manufacturer." Ind. Code § 16-34-2-1. Plaintiffs do not challenge the requirement that mifepristone prescribers complete the REMS Prescriber Certification form, *see* Compl. ¶ 127, much less Indiana's requirement that prescribers retain a copy of that form.

patient's signature.³ Moreover, Indiana's suggestion that "the upshot" of any confusion "may be that Indiana will be effectively enjoined" from enforcing its statute, strains credulity. *See Mot.* at 6. Rather than cast itself as a helpless observer, Indiana has an obvious solution: it could advise its physicians of the continued applicability of state law.

The States' general interest in "protecting the health and safety of their citizens," *Mot.* at 7-9, likewise fails to satisfy the requirements of Rule 24(a). If such generic interests were accepted as sufficiently direct and substantial for purposes of Rule 24, that would grant any State intervention as of right in virtually any litigation against the federal government seeking to enjoin a federal policy. But Rule 24 does not permit a boundless right to intervention: that is why intervention as of right requires that a movant possess more than an "interest" but rather a "'significantly protectable interest.'" *Teague*, 931 F.2d at 261 (citation omitted) (emphasis added). To meet this standard, a movant must demonstrate that it "stand[s] to gain or lose by the direct legal operation of [this] court's judgment on [the] complaint." *Id.* Here, the States have nothing "to lose" from the direct operation of a court judgment that the FDA's regulations (as opposed to their own statutes, which are not at issue) are unconstitutional.

2. Defendants Will Adequately Protect the States' Interests

The States and Federal Defendants share the same objective: to preserve the FDA's restrictions on mifepristone. "When the party seeking intervention has the same ultimate objective as a party to the suit, a presumption arises that its interests are adequately represented, against which the [applicant] must demonstrate adversity of interest, collusion, or nonfeasance." *Virginia*

³ U.S. Food & Drug Admin., *Medical Review of Mifeprex* 43-44, 78-79 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (citing studies finding "no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion" between physicians and other skilled clinicians).

v. Westinghouse Elec. Corp., 542 F.2d 214, 216 (4th Cir. 1976) (citations omitted). In the Fourth Circuit, that presumption is strongest where, as here, the federal government represents the interests of the proposed intervenors. *Stuart v. Huff*, 706 F.3d 345, 351 (4th Cir. 2013) (distinguishing *Trbovich v. United Mine Workers*, 404 U.S. 528 (1972), and imposing heightened standard where defendant is federal government). The States’ Motion fails to address this precedent in their brief, even though Plaintiffs cited it in their email communicating their opposition to this Motion. *See* Mot. at 9-10 (ignoring *Stuart* and relying on *Trbovich*); Email from Plaintiffs’ Counsel to States’ Counsel (June 5, 2020), attached hereto as Exhibit 1.

Contrary to the States’ misleading string cite, *see* Mot. at 12 —comprised largely of out-of-circuit cases in which neither party objected to the intervention⁴—the Fourth Circuit requires an “exacting showing of inadequacy” under the circumstances present here. *Stuart*, 706 F.3d at 351. The States do not, and cannot, establish “identifiable adverse interests with the existing government part[ies]; [that] the existing parties have engaged in collusion; or [that] the government has committed nonfeasance.” *Makhteshim Agan of N. Am., Inc. v. Nat'l Marine Fisheries Serv.*, No. 8:18-CV-00961-PWG, 2018 WL 5846816, at *4 (D. Md. Nov. 8, 2018). Federal Defendants

⁴ *Audubon Naturalist Soc'y of the Cent. Atlantic States, Inc., v. U.S. Dep't of Transp.*, 524 F. Supp. 2d 642 (D. Md. 2007) (motion to intervene by State of Maryland indicating that neither party opposed intervention); *id.* at ECF No. 19 ¶¶ 4, 5; *Wildearth Guardians v. Salazar*, 272 F.R.D. 4 (D.D.C. 2010) (granting Wyoming’s intervention where Plaintiffs did not oppose); *WildEarth Guardians v. Jewell*, 320 F.R.D. 1, 2 (D.D.C. 2017) (“no existing party opposed the intervention”); *Waterkeeper All., Inc. v. Wheeler*, 330 F.R.D. 1, 9 (D.D.C. 2018) (“no opposition”). The two remaining out-of-circuit cases the States cite are readily distinguishable: *Club v. Glickman*, 82 F.3d 106 (5th Cir. 1996), involved a distinct immutable piece of property wholly within the State of Texas, where a judgment forcing USDA to limit agricultural pumping from the Aquifer “will directly interfere with the State’s ability to run its agricultural programs.” *Sierra Club v. Glickman*, 82 F.3d 106, 110 (5th Cir. 1996) (emphasis added). In *Akiachak Native Community v. U.S. Department of Interior*, 584 F. Supp. 2d 1, 7 (D.D.C. 2008), the district court applied the de minimis standard employed in a lawsuit between *private* parties rather than the “very strong showing” standard the Fourth Circuit applies in disputes involving a government agency, *Stuart*, 706 F.3d at 351.

have maintained the in-person dispensing requirement for mifepristone for two decades, and even now in the face of months of petitioning by leading medical authorities for relief during the pandemic. *See* Compl. ¶¶ 55-56, 94-96. The States assert that Defendant FDA does not “share [their] broader interests in regulating the practice of medicine, protecting human life by ensuring that the abortion decision is properly informed, and protecting health and safety by preventing the illegal trafficking of both drugs and humans.” Notice of Intent 2. But even if this were true,⁵ the States ignore the participation of Defendant HHS, the cabinet-level department of the U.S. government responsible for enhancing and protecting the health and well-being of all Americans, Compl. ¶ 34, as well as Secretary Azar, who came to the Administration from Indiana and recently proclaimed his service in “the most pro-life administration in this country’s history.”⁶ In short, there is no reason to believe that Defendants will not vigorously defend the mifepristone REMS, as defense counsel indicated at the June 8, 2020, case management conference that they intend.

The States concede that they share the same ultimate objective as Defendants in upholding the constitutionality of the REMS, but argue that they also seek to “safeguard their own abortion laws.” Mot. at 10. This unequivocally fails to establish adversity under Fourth Circuit precedent. *See, e.g., Stuart*, 706 F.3d at 352 (government agency and proposed intervenors shared ultimate objective because both “want[ed] the [challenged] statute to be constitutionally sustained.”); *Pa. Nat'l Mut. Cas. Ins. Co. v. Perlberg*, 268 F.R.D. 218, 225 (D. Md. 2010) (although upholding the challenged regulations “may lead to different legal and economic circumstances” for movants and

⁵ *See, e.g.*, U.S. Food & Drug Admin., *5 Charged in \$2.8 Million Dark Web Drug Trafficking, Money Laundering Conspiracy* (Jan. 15, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/5-charged-28-million-dark-web-drug-trafficking-money-laundering-conspiracy>.

⁶ U.S. Dep’t of Health & Human Servs., Secretary Azar Statement on March for Life (Jan. 23, 2020), <https://www.hhs.gov/about/news/2020/01/23/hhs-secretary-azar-statement-on-march-for-life.html>.

defendants, “their ultimate objective remains the same”). “[S]tronger, more specific interests do not adverse interests make.” *Stuart*, 706 F.3d at 353.

Likewise, the States’ strategic preferences do not create adversity of interests under Fourth Circuit precedent. The States suggest that Defendants’ defense of this constitutional challenge will be limited to an administrative record created in 2011, *see Mot.* at 10, and tout their own ability to offer live testimony from discredited witnesses,⁷ *see id.* at 10-11. This is triply wrong. *First*, this is not an Administrative Procedure Act matter (so the defense is not confined to the administrative record, which is why Defendants considered proffering live testimony). *Second*, the suggestion that the FDA’s relevant “knowledge” and materials are nearly a decade old, *id.* (emphasis omitted), is plainly false: in 2016, the FDA re-evaluated the REMS as part of its review of the Mifeprex® labeling, *see Compl.* ¶¶ 62, 99, 102;⁸ in 2019, the FDA approved the generic mifepristone and imposed a shared REMS program, *see id.* at ¶ 59 n.12; and over the past three months, the FDA has reviewed and rejected the requests by Plaintiffs and numerous other medical authorities to suspend the in-person dispensing requirement during the pandemic, *see id.* at ¶¶ 94-96. *Finally*,

⁷ See, e.g., *Little Rock Family Planning Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1273, 1282, 1300, 1306-07 (E.D. Ark. 2019) (rejecting the States’ proposed witness Donna Harrison’s unsupported testimony regarding the safety of abortion and noting that Harrison has not practiced in a clinical setting in over 20 years); *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68-69 (N.D. 2014) (concluding that Harrison cannot be deemed a credible witness where her “opinions . . . appear to be shaped primarily by the position she is advocating at the moment . . . lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence”); *Planned Parenthood of Ind. & Ky. v. Comm’r*, 273 F. Supp. 3d 1013, 1036 (S.D. Ind. 2017) (refusing to credit the studies of States’ proposed witness Priscilla Coleman, noting that they “have been almost uniformly rejected by other experts in the field” and that her work had been criticized as having “methodological problems that bring into question both the results and conclusions”) (internal quotation marks and citations omitted); *aff’d*, 896 F.3d 809, 826 (7th Cir. 2019) (rejecting argument by State of Indiana that relied on Coleman’s “controversial and much maligned . . . study”).

⁸ U.S. Food & Drug Admin., Mifeprex (Mifepristone) Tablets (Dec. 15, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020TOC.cfm (hundreds of pages of FDA memoranda from 2016 regarding mifepristone labeling and REMS).

the Fourth Circuit has specifically rejected a finding of adversity of interest where a government entity chose to “rel[y] on legal arguments at the preliminary injunction stage” whereas the proposed interveners would have “presented factual evidence.” *Stuart*, 706 F.3d at 353; *see also*, e.g., *United States v. North Carolina*, No. 1:13CV861, 2014 WL 494911, at *3 (M.D.N.C. Feb. 6, 2014) (choice of legal arguments and how much “to emphasize certain legal arguments at the expense of others” insufficient to establish adversity).

The alignment of objectives between the States and Federal Defendants is dispositive. *See, e.g.*, *Stuart*, 706 F.3d at 352 (rejecting intervention where “[b]oth the government agency and the would-be intervenors want the statute to be constitutionally sustained.”); *Makhteshim*, 2018 WL 5846816, at *4 (rejecting intervention by a group of organizations that had frequently litigated *against* the federal government in other contexts, where the intervenors shared the same ultimate objective as the federal defendants); *Outdoor Amusement Bus. Ass’n v. Dep’t of Homeland Sec.*, No. CV ELH-16-1015, 2017 WL 2778820, at *11 (D. Md. June 26, 2017) (rejecting intervention by companies and associations utilizing federal visa program where intervenors shared same ultimate interest as federal defendants in upholding regulations, even if individual motivations differed); *Brackeen v. Zinke*, No. 4:17-CV-00868-O, 2018 WL 10561984, at *3 (N.D. Tex. June 1, 2018) (rejecting intervention by Navajo Nation, including based on tribe’s “interest in making sure its tribal enrollment requirements are upheld as constitutional,” where tribe shared same ultimate objective as federal defendants to defend constitutionality of challenged law); *Mir v. Smith*, 521 F. Supp. 446, 449 (N.D. Ga. 1981) (rejecting intervention by State of Florida where state lacked the “expertise” held by the federal defendant with regard to screening of immigrants, and adversity between the state and federal government in other pending litigation relating to immigration “cannot be decided by this federal district court in Atlanta”).

B. Permissive Intervention Should Be Denied Because Adding Ten States as Parties Rather than *Amici* Will Unduly Complicate Resolution of This Urgent Matter While Offering No Countervailing Benefit.

The States alternatively seek permissive intervention, which a court may grant only where a party has a “claim or defense that shares with the main action a common question of law or fact.” Fed. R. Civ. P. 24(b); *accord* Mot. at 12. The States failed to comply with Rule 24(c)’s requirement that their motion be “accompanied by a pleading that sets out the claim or defense for which intervention is sought,” Fed. R. Civ. P. 24(c), and in their memorandum assert only a “defense” of their *own* statutes—which this litigation does not challenge. Mot. at 13. This failure is dispositive: even assuming the States have “sufficient[ly] . . . apprise[d]” Plaintiffs of their defenses as required by Rule 24(c), *see Spring Const., Co. v. Harris*, 614 F.2d 374, 377 (4th Cir. 1980), they have not identified any defense of the federal restrictions actually challenged in this litigation, as required by Rule 24(b).

But even assuming *arguendo* that these threshold requirements are met, permissive intervention is not warranted. In making this discretionary determination, the Court must balance any prejudice against any advantages, *Makhteshim*, 2018 WL 5846816, at *6; Fed. R. Civ. P. 24(b)(3), and here, the balance weighs heavily against adding the States as parties. Adding ten states to this litigation as defendants rather than *amici*—and increasing the total number of parties from nine to 19—will “necessarily complicate” matters while adding no substantive value. *Stuart*, 706 F.3d at 355; *see also Virginia.*, 542 F.2d at 217 (denying intervention by State of Virginia based in part on “potential unmanageability” of the litigation, noting that “[a]t least thirteen other states are possible litigants”). This is particularly so where the States here seek to intervene for the precise purpose of interjecting speculative questions about state laws that Plaintiffs do not challenge. Adding the States as parties to offer evidence on their motivations for imposing state

abortion restrictions that go beyond what the REMS require, will needlessly distract from and complicate resolution of the narrow constitutional questions Plaintiffs present.⁹ See *N.C. State Conference of NAACP v. Cooper* 332 F.R.D. 161, 172 (M.D.N.C. 2019) (intervenors “would likely detract from, rather than enhance, the timely resolution, clarity, and focus on, solely the weighty and substantive issues to be addressed in this case”).

Federal Defendants are more than adequate representatives of the States’ interests. See *Va. Uranium, Inc. v. McAuliffe*, No. 4:15-CV-00031, 2015 WL 6143105, at *4 (W.D. Va. Oct. 19, 2015) (“[W]here . . . intervention as of right is decided based on the government’s adequate representation, the case for permissive intervention diminishes or disappears entirely.”); *Stuart*, 706 F.3d at 355 (no meaningful benefit to intervention where “the existing [d]efendants are zealously pursuing the same ultimate objectives”). Instead, “[t]o the extent that [the States] have special expertise they believe that they bring to the defense of [the in-person dispensing requirement], such expertise can be provided through the submission of *amicus* briefs.” *NAACP*, 332 F.R.D. at 172; see also *McHenry*, 677 F.3d at 227 (“Numerous cases support the proposition that allowing a proposed intervenor to file an *amicus* brief is an adequate alternative to permissive intervention”) (collecting cases).

CONCLUSION

Accordingly, Plaintiffs respectfully request that the Court deny the Motion to Intervene.

⁹ For instance, Indiana and Arkansas highlight their laws prohibiting physicians from prescribing or dispensing mifepristone past the gestational limit that is part of the treatment regimen included in the FDA-approved drug labeling. See Mot. at 2-3; Notice of Intent at 1. But Plaintiffs do not challenge the treatment regimen in the labeling, so this issue is no more than a distraction.

Dated: June 10, 2020

Respectfully submitted,

/s/ John A. Freedman

**AMERICAN CIVIL LIBERTIES UNION
FOUNDATION**

Julia Kaye*
Anjali Dalal*
Ruth Harlow*
Rachel Reeves*
Jennifer Dalven*
125 Broad Street, 18th Floor
New York, NY 10004
(212) 549-2633
(212) 549-2650 (fax)
jkaye@aclu.org
adalal@aclu.org
rharlow@aclu.org
rreeves@aclu.org
jdalven@aclu.org

Lorie Chaiten*
1640 North Sedgwick Street
Chicago, IL 60614-5714
rfp_lc@aclu.org

**ARNOLD & PORTER KAYE SCHOLER
LLP**

John A. Freedman (D. Md Bar. No 20276)
R. Stanton Jones (D. MD. Bar No. 20690)
David J. Weiner*
Jocelyn A. Wiesner*
Andrew Tutt*
Gina Colarusso*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com
stanton.jones@arnoldporter.com
david.weiner@arnoldporter.com
jocelyn.wiesner@arnoldporter.com
andrew.tutt@arnoldporter.com
gina.colarusso@arnoldporter.com

**Pro hac vice*

Counsel for Plaintiffs American College of Obstetricians and Gynecologists, Council of University Chairs of Obstetrics and Gynecology, New York State Academy of Family Physicians, Honor MacNaughton, M.D., and SisterSong Women of Color Reproductive Justice Collective

CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5.

/s/ John A. Freedman
John A. Freedman
601 Massachusetts Ave., NW
Washington, D.C., 20001
T: (202) 942-5000
john.freeman@arnoldporter.com